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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/254,966

03/16/99

CORREA

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MO-5092/LEA

HM12/0512

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EXAMINER

WINKLER, U

ART UNIT

PAPER NUMBER

1645

7

DATE MAILED:

05/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/254,966

Applicant(s)

CORREA ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 13-27 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other:

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DETAILED ACTION

This Office Action is the response to applicant's amendment filed 17 April 2000. Claims 1-8 and 13-27 are pending under final rejection.

The text of those sections of Title 35 U.S.C. not included in this action can be found in a prior office action.

Acknowledgment is made of the submission of a computer readable disk for the sequence listing.

Acknowledgement is made of the submission of an Information Disclosure statement filed 17 March 2000 as Paper No.5.

The objection of claim 6 is **maintained** because of the grammar informalities, the claim should read "peptides as defined in claim 1". The amendments filed 17 April 2000 do not alleviate the grammar and dependence informality.

Claim Rejections - 35 USC § 112

The rejection of claims 1, 4, 5, 13 and 14 under 35 U.S.C. 112, second paragraph, as being indefinite is **withdrawn** due to applicant's arguments and amendments.

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The rejection of claims 24-27 under 35 U.S.C. 112, second paragraph, as being indefinite **is maintained**, because applicant's amendments did not rectify the rejection and the amendment added language that did not clarify the problem of indefiniteness. Please see the grounds for new rejection below.

Claim Rejections - 35 USC § 101

The rejection of claim 24-27 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter **is withdrawn** due to applicant's amendments.

Claim Rejections - 35 USC § 103

The rejection of claims 1-8, and 13-21 under 35 U.S.C. 103(a) as being unpatentable over Zamorano et al. (Virology 1995) and Rodriguez et al. (Arch. Virol. 1994) **is maintained**.

Applicant's arguments have been fully considered but are not persuasive. Applicant asserts that the lack of immune response to the non-structural protein in the heat killed whole virus vaccine would not have motivated the ordinary artisan to make peptides against the non-structural proteins. This is not persuasive because it is not the heat killed whole virus vaccine that provides the motivation for developing the peptide based vaccine against the non-structural proteins. The motivation to produce a peptide based vaccine to the non-structural proteins of FMDC comes from the differences between the heat killed vaccine and the natural infection. It is notoriously well accepted in the art that a natural viral infection will create the best immune response and thereby provide the best protection against re-infection by the same virus. Based

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on the teachings of Rodriguez et al. it would have been prima facie obvious to one of ordinary skill in the art to produce a peptide based vaccine to those portions of the virus that are recognized by the natural infection because the immune system responds to them in providing protection. Based on the teachings of Zamorano et al., one of ordinary skill in the art would have an expectation of success in eliciting an immune response to peptides. Therefore, applicant's arguments are not deemed persuasive and the rejection **is maintained**.

The rejection of claims 1-8 and 13-23 under 35 U.S.C. 103(a) as being unpatentable over Zamorano et al. (Virology 1995) and Rodriguez et al. (Arch. Virol. 1994) in view of Morgan et al. (Am. J. Vet. Res. 1990) **is maintained**.

Applicant's arguments have been fully considered but are not persuasive. The alleged deficiencies Zamorano et al. and Rodrigues et al. have been addressed above, therefore applicants traversal of the rejection is not persuasive. The applicant contends that the fusion protein disclosed by Morgan et al. is not suggestive of the vaccine containing non-structural peptides as recited in the claims. Claims 7, 25 and 27 recite that the peptides may be modified by coupling to a carrier. The examiner does not agree with the applicant's suggestion that the fusion protein taught by Morgan et al. is not suggestive of the vaccine disclosed in the instant application. The fusion protein taught by Morgan et al. is a peptide coupled via an amide bond to a protein that serves as a carrier. Therefore, applicant's arguments are not deemed persuasive and the rejection **is maintained**.

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The rejection of claims 1-8 and 13-27 under 35 U.S.C. 103(a) as being unpatentable over Zamorano et al. (Virology 1995) and Rodriguez et al. (Arch. Virol. 1994) in view of Lubroth et al. (Vaccine 1996) is **maintained**.

Applicant's arguments have been fully considered but are not deemed persuasive. The alleged deficiencies Zamorano et al. and Rodrigues et al. have been addressed above, therefore applicants traversal of the rejection is not persuasive. Applicant discloses that Lubroth et al. does teach a method of distinguishing between non-vaccinated and convalescent cattle, distinguishing between vaccinated and convalescent animals has important agricultural consequences. Therefore, applicant's arguments are not persuasive and the rejection is **maintained**.

Applicant should note that the claim numbering of the Office Action from 1/18/200 differs from applicant's responses.

New grounds of rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. The ordinary artisan would not know what is meant by “an article of matter”.

Applicant should amend the claim to the conventional term: “a composition”.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached on 8:30 am - 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned are 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Ulrike Winkler, Ph.D.



JEFFREY STUCKER
PRIMARY EXAMINER